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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,014	03/24/2004	Jeffrey Roger Granett	P31824C1D1C1	5692

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,014	GRANETT ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 24, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/24/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment

The preliminary amendment filed 24 Mar 2004 is noted as amending the specification at page 1; canceling claims 1-21; and presenting new claims 22-41. The status of the listed applications at page 1 of the specification should be updated to reflect their current status.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on March 24, 2004 was received and has been considered together with the remarks.

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

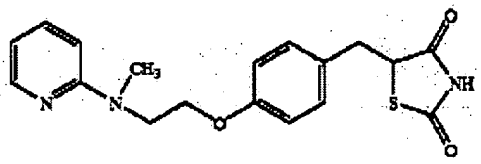
Claims 22-41are rejected under 35 U.S.C. 102(e) as being anticipated by Hindley US 6,686,475 B2.

Hindley discloses a method for the treatment of Type II diabetes (column 1 lines 33+) in a human (column 10 line 31+), which comprises administering substituted-thiazolidinedione derivates such as 5-[4-[2(N-methyl-N-(2pyridyl)amino)ethoxy]lbenzyl]thiazolidine,4-dione (example 30 column 37 line 25+) l- or a pharmaceutically acceptable salt or solvate thereof (column 9 line 59+), wherein the solvate is a hydrate (column 4 lines 59-60) from 1 to 6 times a day (column 10 lines 63 +) which includes from 1 to 2 times a day in an amount of from 0.1 to 1500 mg (column

11 lines 1-3) which includes from 2 to 8 mg. The method includes administering the compound in a pharmaceutical acceptable form such as a tablet or a capsule (column 10 line 15) having a pharmaceutically acceptable carrier such as starch glycollate (column 10 line 23), microcrystalline cellulose (column 10 line 23), polyvinylpyrollidone (column 10 line 24) or sucrose (column 10 line 25).

EXAMPLE 30

5-(4-[2-(N-Methyl-N-(2-pyridyl)amino)ethoxy] benzyl)-2,4-thiazolidinedione



Consequently, the reference anticipates the claimed invention defined in claims 22-41. Regarding dosage, this can be regulated by the physician treating the patient in need of.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heyman et al. U.S. Patent No. 5,972,881 ('881) in view of Lohray et al. US 5,801,173 ('173), and Smith US 6,166,049 ('049).

Heyman *et al.* teaches the current claims drawn to a method of treating type II diabetes in a human, comprising administering 2 to 8 mg of 5-[4-[2(N-methyl-N-(2pyridyl)amino)ethoxy]lbenzyl]thiazolidine-z,4-dione (troglitazone or pioglitazone) as in claims 22 and 24 in a pharmaceutically acceptable form (salt) at column 18 lines 6+, to a human in need of such treatment. Heyman et al. teach treatment of NIDDM (type II diabetes) with thiazolidinedione compounds (see abstract) such as BRL 49653 (rosiglitazone) (column 1, lines 19-58) in a pharmaceutically acceptable carriers such as lactose, hydroxypropylmethyl cellulose, CMC and or PVP, sodium alginate, etc. (see column 13, line 18 to column 14, line 63), and the solvate to be hydrate as in current claim 25 at column 3 line46-47. The '881 patent also teach claim of administering the compound in the form of a tablet or a capsule taught at column 13 lines 46+, as in current claims 29 and 30, in a pharmaceutically acceptable carrier (claim 31) at column 13 lines 43+, where the carrier comprises of a disintegrant-starch (claim 32, 39) at column 14 line 38, methyl cellulose as in current claim 34, column 14 line 36,, a cellulose (claim 35) at column 14 line 33, and the pharmaceutically acceptable carrier

comprises of a binding agent –gelatin gum etc at column 14 line 35. Regarding the dosing up to 6 times per day, Heyman et al. teach that repeated administration of BRL 49653 to obese mice improves glycemic control by increasing insulin responsiveness of target tissues (column 5, lines 52-58).
The '881 patent also teach as in current claim 41 of the pharmaceutically accepted carries to be sugar, maize etc taught at column 14 lines 33+.

Lohray et al teach, administering a derivative of thiazolidinedione in their tautermeric forms for the treatment of type II diabetic at column 12 line 41, their pharmaceutically acceptable solvates column 12 line 35, wherein the salt is maleate at column 12 line 21, administered in the form of a tablet or capsule at column 12 line 53+, the dosage to be in the range of 0.1-10 mg per day as a single or double dose which falls within the range of the current claim 1 taught at column 13 lines 4+.

Smith teaches administration of a similar drug structure for the treatment of type II diabetes at column 2 lines 45+.

The claims differ in that the '881 patent did not per se teach of the dosage administration per day, nor maleate as the salt.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teaching of Heyman with that of Lohray to administer the drug based on the body weight of the patient, as disclosed by Lohray, at column 13 lines 7+ the drug generally is administered in small doses and increments thereof. Additionally once a method or a compound composition is known within the skill of the artisan to determine the optimum range. As anyone of ordinary skill in the art

will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude', for instance, an extremely heavy patient or one having severe diabetes would require a correspondingly higher dosage, or multiple doses per day.

One of ordinary skill would have expected successful results with the tablet for the treatment of type II diabetes as the drugs are well known in the art and have improving success with the different tautermeric forms, therefore one of ordinary skill in the art would know that using 5-[4-[2(N-methyl-N-(2pyridyl)amino)ethoxy]lbenzyl]thiazolidine-z,4-dione to treat type II diabetes would be of success. The cited prior art would motivate one of skill to choose any of the tautermeric forms for the treatment of the disease. Thus the claims are deemed prima facia obvious over the cited prior art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00 Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
06/29/05

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